UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,794	09/03/2003	Steve Gara	THR-5007	6964

34132 7590 04/13/2006

COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,794	GARA ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 16-25* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/19/05, 8/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 10 February 2006 is acknowledged. The traversal is on the ground(s) that the Group II methods of making the apparatus include limitations drawn to the Group I apparatus. This is not found persuasive because the molding operation claimed in Group II does not require all the particular details of the claimed invention of Group I, demonstrating that the method of Group II may be used to construct a materially different apparatus than claimed in Group I. Furthermore, applicant cancelled nonelected claims 12-15.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The references cited by applicants in the information disclosure statements filed 1 August 2005 and 19 May 2005 have been made of record. Examiner has considered the voluminous references to the best of her ability.

3. While the statements filed do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the eliminaiton of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 do not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion

in a long list of citations may not comply with Applicant's duty of disclosure. *See* Penn Yan Boats, Inc. v. Sea Lark boats Inc., 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

4. Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

> *Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability.* MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

> *It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See* Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). *See also* MPEP § 2004.

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by

37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,676,644 to Toavs et al.

In the specification and figures, Toavs discloses the apparatus as claimed by applicant. In particular, Toavs discloses a cassette assembly 110 for a blood processing machine with rigid plastic plates 112, 114 serving as the housing, five outwardly extending tubing loops interconnecting passageways in the cassette and additional, non-looped tubing extending from the cassette (see column 16, lines 37-45, FIG 2A). The cassette further includes flexible tubing lines that are exposed via window 118 (see FIG 2B) to an interfacing valve assembly (1110, 1120, see FIG 3) that may selectively occlude the tubing lines, preventing fluid flow therethrough (see column 12, lines 15-30). The cassette comprises multiple hubs (unlabeled in FIG 2A, see increased-diameter portion between tubing lines 192,122,132,162,142 and cassette frame 116, FIG 2B, labeled as connectors 360, 492,520,392,456 in FIG 16) that connect at least 5 tubing loops of flexible tubes.

With regard to claim 4, Toavs discloses that the tubing lines in rigid cassette 110 are exposed via window 118 with an interfacing valve assembly that operates to occlude fluid flow through the tube when pressure is exerted against the tube. Applicant's recitation that the housing is "adapted to" resist the pressure exerted against the tubing is not a structural limitation that distinguishes the present invention from the prior art device disclosed by Toavs. The cassette housing disclosed by Toavs is capable of resisting the pressure exerted by the occluders on the tubing, since the device is designed to occlude fluid flow by means of exerting pressure on the tubing lines.

With regard to claim 9, Toavs discloses that the blood inlet passageway of the cassette 110 comprises filter 136 (see column 17, lines 1-5).

With regard to claim 16, Toavs discloses a centrifuge channel assembly or bowl 200 in communication with the cassette 110. The centrifuge assembly comprises an outer channel housing 206 with a bottom plate 204, and an opening or core 328. The core comprises a lumen or tube jacket 548 through which tubing connects between blood processing vessel 352 and cassette 110 (see FIG 8, columns 46-48). The channel assembly 200 comprises a first bowl channel or blood inlet slot 224 that communicates with flexible blood inlet tube 412, a second bowl channel or plasma outlet slot 256 communicating with flexible tubing 476, and a third bowl channel or red blood cell slot 272 communication with flexible tube 540.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 5, 7, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,676,644 to Toavs et al, as applied above.

In the specification and figures, Toavs discloses the apparatus substantially as claimed by applicant with the exception of the number of apertures in the cassette and the occluder bar molded into the housing of the cassette.

Toavs discloses that the cassette comprises sufficient tubing and aperture space to control an apheresis procedure. It would have been obvious to one having ordinary skill in the art at the time of invention to separate the single aperture 118 disclosed by Toavs into multiple apertures as claimed by applicant. Applicant has not disclosed that the multiple apertures solve any stated problem or are for any particular purpose, and it appears that the invention would perform equally well with a single aperture. It has been held that constructung a formerly integral structure into various elements involves only routine skill in the art. See MPEP § 2144.04.

Claims 5 and 8 recite that the housing (of the cassette) comprises at least one molded occluder bar. The examiner notes that it is the housing of the machine in Toavs that comprises the occluder bar and not the cassette housing. However, Toavs specifically discloses that the occluding members 1400a, 1400b, and 1400c occlude

tubing members 82, 146, 92, and 166 by pushing the tubing against opposing occluding walls 1104, 1106, 1114, 1116, 1124, and 1126 in the same manner as that of applicant's invention, which pushes tubing lines against opposing occluder bars in order to halt flow through the tubes. Since the occluder bars serve the same function in both the prior art and applicant's invention, the only difference between the Toavs device and applicant's cassette is the location of the occluder walls or bars—which are located on the machine 6 in the Toavs device and in the cassette in applicant's invention. It has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP § 2144.04. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to move the occluding walls from the blood separator to the cassette, since the walls would function in the same manner in both locations.

With regard to claim 8, applicant's cassette is "adapted to" allow the interaction between the actuator, tubing and the occluder bar is not a structural limitation that distinguishes the present invention from the modified prior art device disclosed by Toavs. With the rearrangement of the occluder bar from the blood separation device to the cassette, as set forth above, the Toavs device is capable of operating as claimed by applicant, rendering the instant invention unpatentable over the Toavs device.

9. Claims 17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,676,644 to Toavs et al, as applied above, in view of US 4,573,962 to Troutner.

In the specification and figures, Toavs discloses the device substantially as claimed by applicant with the exception of an irradiation chamber. Troutner discloses a blood treatment device the centrifugally separates blood into its constituent components, and then sends an enriched leukocyte portion, with plasma and buffy coat, to an irradiation chamber for treatment. The device is designed to centralize separation and treatment devices into a single unit for ease of use and cost savings (see column 3, lines 20-35). In particular, Troutner discloses that blood is removed from a patient, routed through tubing apparatus 10 to centrifuge 13 for separation. After separation, the blood is moved via tube 24' to treatment cassette and irradiation chamber 120, and removed from the chamber via tube 36.

It would have been obvious to add tubing lines and an irradiation chamber as disclosed by Troutner to the blood separation assembly disclosed by Toavs in order to provide centralized leukocyte treatment for disease in an efficient treatment device to reduce cost and physical trauma to the patient, as taught by Troutner.

With regard to claim 19, Troutner discloses that there is a prime solution bag 34, and an anticoagulant bag 20, both with tubing connected to the bags (see column 6, lines 26-45). Priming solution is often saline (see Toavs column 34, lines 62-67). The assembly further comprises plasma collection bag 22, treated fluid bag 35, and an irradiation chamber that allows fluid flow from blood processing and separation apparatus 10. Toavs specifically discloses that extracorporeal tubing set 10 removes and returns blood between the system and the patient via needle subassembly 30 (see Toavs column 16, lines 10-37).

With regard to claim 20, both Toavs and Troutner disclose a processing apparatus or tower that holds the blood processing fluid pathways. In particular, Toavs discloses blood component separation device 6 with a pump/valve/sensor assembly 1000. The device or tower comprises peristaltic pump assemblies 1020, 1030, 1040, 1060, and 1090 that engage the pump loops (see column 19, lines 33-57), cassette mounting plate or deck 1010 with valves that exert pressure on the tubing in the cassette, and a centrifuge chamber 352. Toavs does not disclose a photoactivation cavity, but Troutner discloses cassette drawer assembly 17 for photoactivation of separated blood components.

With regard to claim 21, Troutner discloses that the irradiation chamber is substantially vertical, but discloses that the inlet is at the bottom and outlet at the top of the chamber (see FIG 4). However, applicant does not disclose any criticality for the location of the inlet and outlet of the irradiation chambers. Both the prior art and applicant's invention place the inlet and outlet at opposite ends of the chamber, allowing the fluid to traverse the length of the chamber. Applicant's invention functions in the same manner as the prior art, indicating that the location of the inlet and outlet of the chamber is not critical to the invention. Absent any showing of criticality or unexpected results, such a mere reversal of the working parts of a device in the prior art is an obvious modification of the prior art, since it involves only routine skill in the art. See MPEP § 2144.04.

With regard to claim 22, Troutner specifically illustrates supports 15, 18, for the prime bag, treated fluid bag, plasma bag, and anticoagulant bag (see FIGS 1, 2, column 7, lines 56-65).

With regard to claim 23, Toavs illustrates five pump loops and pump heads (see FIG3). Toavs discloses that the cassette comprises sufficient aperture space to control an apheresis procedure. It would have been obvious to one having ordinary skill in the art at the time of invention to separate the single aperture 118 disclosed by Toavs into multiple apertures as claimed by applicant. Applicant has not disclosed that the multiple apertures solve any stated problem or are for any particular purpose, and it appears that the invention would perform equally well with a single aperture. It has been held that constructung a formerly integral structure into various elements involves only routine skill in the art. See MPEP § 2144.04. With regard to the occluder bars, the examiner notes that it is the housing of the machine in Toavs that comprises the occluder bar and not the cassette housing. However, Toavs specifically discloses that the occluding members 1400a, 1400b, and 1400c occlude tubing members 82, 146, 92, and 166 by pushing the tubing against opposing occluding walls 1104, 1106, 1114, 1116, 1124, and 1126 in the same manner as that of applicant's invention, which pushes tubing lines against opposing occluder bars in order to halt flow through the tubes. Since the occluder bars serve the same function in both the prior art and applicant's invention, the only difference between the Toavs device and applicant's cassette is the location of the occluder walls or bars—which are located on the machine 6 in the Toavs device and in the cassette in applicant's invention. It has been held that rearranging parts of an

invention involves only routine skill in the art. See MPEP § 2144.04. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to move the occluding walls from the blood separator to the cassette, since the walls would function in the same manner in both locations.

With regard to claim 24, Toavs discloses flexible tubing from the patient to the cassette and five pump loops that pump anticoagulant, whole blood, separated fractions, and returned blood (see column 19, lines 33-65). Applicant's recitation of the function of each of the loops is a statement of the intended use of the device. The flexible tubing and pump loops of the Toavs device are capable of being operated in the manner claimed by applicant according to the desired blood processing procedure. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

10. Claims 18 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,676,644 to Toavs et al, as applied above, in view of US 4,737,140 to Lee.

In the specification and figures, Toavs discloses the device substantially as claimed by applicant with the exception of an irradiation chamber with plates as claimed by applicant. Lee discloses a blood separation and treatment device, incorporating by reference all the limitations of US 4,573,962 to Troutner (see column 2, lines 53-56). Lee's device incorporates irradiation treatment in a blood separation device in order to accurately target the diseased cells and reduce treatment time and cost with a disposable irradiation chamber.

Lee discloses that the irradiation chamber comprises flexible tubing inlet 501, flexible tubing outlet 502, and male and female thin plate sections (see FIG 4, column 10, lines 43-67). The plates are comprised of polycarbonate, a rigid material, and comprises periodic protrusions within the plate to maintain the position of the tubing within the plate. While Lee does not specifically disclose that each plate carries raised partitions, Lee teaches that the male and female plates cooperate to form a pathway, indicating that the protrusions disclosed by Lee on one plate interact with a similar structure on the second plate, creating the same functional relationship between the plates as claimed by applicant.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the irradiation chamber disclosed by Lee in the blood separation and treatment system disclosed by Toavs, in order to provide an integrated treatment system with reduced treatment time and cost, as taught by Lee.

With regard to claim 11, Lee discloses that the treatment cassette may comprise an integrated circuit memory device 506506 which examiner is interpreting to be equivalent to applicant's claimed smartcard. The memory device may retain cassette parameters and prior usage information (indicating that the memory device may receive information from the treatment device) and connects to the central control processor, which is a means for recording data to the memory device (see column 10, lines 59-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a memory device as disclosed by Lee to the

blood processing cassette disclosed by Toavs in order to identify the parameters of the cassette and treatment protocol, as taught by Lee.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,676,644 to Toavs et al in view of US 4,573,962 to Troutner, as applied above, further in view of US 4,737,140 to Lee.

Toavs and Troutner disclose the apparatus substantially as claimed by applicant with the exception of the recordable smartcard. Lee discloses that the treatment cassette may comprise an integrated circuit memory device 506 which examiner is interpreting to be equivalent to applicant's claimed smartcard. The memory device may retain cassette parameters and prior usage information (indicating that the memory device may receive information from the treatment device) and connects to the central control processor, which is a means for recording data to the memory device (see column 10, lines 59-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a memory device as disclosed by Lee to the blood processing cassette disclosed by Toavs and Troutner in order to identify the parameters of the cassette and treatment protocol, as taught by Lee..

Allowable Subject Matter

12. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose or suggest the method claimed by applicant. In particular, the prior art fails to disclose a method of photopheresis using the claimed apparatus along with the steps of pumping red blood cells to push buffy coat out of the bowl into the buffy coat collection bag, and discontinuing collection of buffy cells when red cells are detected, along with the other steps and limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICIA BIANCO
PRIMARY EXAMINER
4/12/06

Leslie R. Deak
Patent Examiner
Art Unit 3761
10 April 2006